

REMARKS

Claims 1-4, 6-9, 19-27, 29, 30 and 35-38 are currently pending in this application. Claims 5, 10-18, 28 and 31-34 have been canceled. Claims 1, 3, 4, 19, 29 and 35 have been amended. New claims 36-38 have been added. Applicants have carefully reviewed the final Office Action and respectfully request reconsideration of the claims in view of the remarks presented below.

Double Patenting

In view of the lack of indication of patentable subject matter in the present application, Applicants prefer to hold the filing of a Terminal Disclaimer in abeyance.

Claim Rejections Under 35 U.S.C. §102

Claims 1-3, 6-9, 19-27 and 30 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,415,183 (Scheiner).

Independent claim 1 recites sensing respiratory information during a respiratory cycle related to tidal volume and upper airway patency; based at least in part on the respiratory information, determining if tidal volume is less than a limit; based at least in part on the respiratory information, determining if upper airway patency is inadequate; if the tidal volume is less than the limit and upper airway patency is not inadequate, calling for diaphragm activation at a stimulation power based on an increasing monotonic relationship with respect to increasing tidal volume; and if the tidal volume is less than the limit but upper airway patency is inadequate, inhibiting diaphragm activation. Independent claim 19 is an apparatus claim reciting structure for performing features of claim 1.

Scheiner discloses delivering stimulation pulses of a constant power to the phrenic nerve. The power level is set during implant. See e.g., column 7, lines 1-5. Scheiner does not disclose any relationship between minute ventilation/tidal volume and stimulation-pulse power, whereby stimulation-pulse power is changed from its constant level. More specifically, Scheiner does not disclose diaphragm stimulation power that is

based on an increasing monotonic relationship with respect to increasing tidal volume, as recited in claims 1 and 19. Furthermore, Scheiner discloses monitoring minute ventilation/tidal volume for indication of Cheyne-Stokes respiration and sleep apnea and delivering diaphragm stimulation in both cases. See e.g., column 7, lines 15-28 and column 8, lines 24-32. As noted in Applicants' specification at paragraph [0104], apnea may be associated with inadequate upper airway patency. Thus Scheiner appears to teach delivering diaphragm stimulation in the presence of inadequate upper airway patency. This is contrary to claims 1 and 19, each of which include the feature of inhibiting diaphragm stimulation when upper airway patency is inadequate.

In view of the foregoing, Applicants submits that Scheiner fails to disclose the combination of elements and features recited in independent claims 1 and 19. Accordingly, Applicants request reconsideration of the §102 rejections of claims 1 and 19. Applicants further submit that, by virtue of the incorporation of subject matter recited in their respective independent base claim, each of dependent claims 2-3, 6-9, 20-27 and 30 is also novel over Scheiner.

Claim Rejections Under 35 U.S.C. §103

Claims 5, 10, 11, 18, 28 and 29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Scheiner in view of U.S. Patent No. 4,830,008 (Meer). Claim 4 was rejected under 35 U.S.C. §103(a) as being unpatentable over Scheiner in view of U.S. Patent No. 6,251,126 (Ottenhoff).

Claims 5, 10, 11, 18 and 28 have been canceled. Regarding claim 29, in view of the foregoing analysis of independent claim 19 in view of Scheiner, Applicants believe that the rejection of claim 29 under §103 is moot as claim 29 depends from allowable independent claim 28.

That said, regarding the basis for rejection of claim 29, Meer is concerned with upper airway patency and teaches the delivery of stimulation to upper airway muscles to maintain upper airway patency. Meer does not teach or suggest adjusting the level or power of the stimulation delivered to the upper airway muscles. Scheiner is concerned

with treating respiratory disorders and teaches delivery of diaphragm stimulation in response to sleep apnea (which as stated above may be associated with inadequate upper airway patency). Like Meer however, Scheiner does not teach or suggest adjusting the level or power of the stimulation delivered to the diaphragm. Thus, neither Meer nor Scheiner, either alone or in combination, teach or suggest adjusting stimulation power. Because neither teaches adjusting stimulation power, it is unreasonable to opine that the combination of the two somehow suggests the same.

Furthermore, once Applicant has taught his innovative method involving adjusting diaphragm stimulation power based at least in part on information related to upper airway patency, such method may by hindsight seem to yield a predictable result to one having ordinary skill in the art. However, when viewed as of the time Applicants' invention was made, and without the benefit of Applicants' own disclosure, there is nothing in the art of record which realistically predicts Applicants' inventive approach.

Claim 35 was rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Publication 2005/0085865 (Tehrani).

Claim 35 recites sensing respiratory information related to tidal volume; based at least in part on the respiratory information, determining if tidal volume is between an upper limit and a lower limit; and if the tidal volume is between the upper limit and the lower limit, calling for diaphragm activation at a stimulation power based on a decreasing monotonic relationship with respect to increasing tidal volume and, if the tidal volume is less than the lower limit, calling for diaphragm activation at a stimulation power based on an increasing monotonic relationship with respect to increasing tidal volume.

Tehrani discloses increasing pulse parameters to obtain a desired tidal volume. See paragraph [0071]. Tehrani does not teach or suggest determining if tidal volume is between an upper limit and a lower limit. Nor does it teach or suggest the use of two different stimulation power relationships based on where the tidal volume is with respect to the upper and lower limits. More specifically, Tehrani does not teach or suggest selecting pulse parameters based on decreasing monotonic relationship with respect to

increasing tidal volume when the tidal volume is between the upper and lower limits and selecting pulse parameters based on increasing monotonic relationship with respect to increasing tidal volume when the tidal volume is less than the lower limit.

In view of the foregoing, Applicants submits that independent claim 35 is patentable over Tehrani. Accordingly, Applicants request reconsideration of the §102 rejection of claim 35.

New Claims 36-38

New dependent claim 36 is similar to claim 29 and is believed to be patentable for the same reasons as claim 29.

New dependent claim 37 recites delivering stimulation approximately at the beginning of the inspiratory phase of a next respiratory cycle. New independent claim 38 recites first and second expiratory flow limits and first and second inspiratory flow limits that are used in conjunction with respiratory information to either deliver diaphragm stimulation or inhibit diaphragm stimulation. The prior art of record does not disclose the combination of features recited in claims 37 and 38.

CONCLUSION

Applicants have made an earnest and bona fide effort to clarify the issues before the Examiner and to place this case in condition for allowance. Therefore, allowance of Applicants' claims 1-4, 6-9, 19-27, 29, 30 and 35-38 is believed to be in order.

Respectfully submitted,

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Date


David S. Sarisky
Attorney for Applicant
Reg. No. 41,288
818-493-3369

CUSTOMER NUMBER: 36802